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ORIGINAL RESEARCH

Membrane obturators as alternative to rigid obturators in soft palate defects: The VELOMEMBRANE pilot study

Adrien Naveau, DDS, PhD[1]*, Adrien Laran, DDS[1], Mathieu Carrière, DDS[1], Valérie Plaire[1], Elise Arrive,DDS, PhD[1], Christophe Bou,DDS, PhD[1]

[1]Department of Oral Medicine and Oral Surgery, CHU Bordeaux, F-33000 Bordeaux, France.

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Corresponding Author:

Prof. Adrien Naveau

Unité de Parodontologie et Prothèse Dentaire, Service de Médecine Bucco-Dentaire, Hôpital Saint André

1 Rue Jean Burguet, 33000 Bordeaux, France.

Phone: +33 5 57 62 34 34

Email:

adrien.naveau@chu-bordeaux.fr

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ABSTRACT

Purpose: The purpose of this study was to assess the efficacy of a membrane obturator using a thick dental dam. The objectives were to compare speech handicap levels, swallowing handicaps, and the health-related quality of life in patients wearing the membrane obturator and the rigid obturator.

Materials and Methods: The VELOMEMBRANE trial was designed as a superiority, open-label, two-way, random crossover clinical trial. Adult patients exhibiting velar or palatovelar defects after tumor resection and requiring rigid obturator-mediated prosthetic rehabilitation were recruited. The participants were randomly allocated an order for wearing both prostheses for two 1-month periods. Outcomes were reported by completing questionnaires such as the Voice Handicap Index (VHI), the Deglutition Handicap Index (DHI) and health-related quality of life scores of the European Organization for Research and Treatment of Cancer (EORTC).

Results: One inclusion center had to close during the Covid-19 pandemic outbreak. Only 4 of the 14 patients could be recruited during the time of the study. These preliminary results showed that defects characterized by a full resection of the soft palate could benefit from the new system. However, the traditional rigid obturators were often more satisfactory. The main issue with the new membrane obturator was the need for almost-daily membrane change.

Conclusions: This study documented the utility of this new medical device. With future improvement in the membrane biomaterial, this system may greatly improve the management and quality of life of patients with some specific types of acquired velar insufficiency. (*Int J Maxillofac Prosthetics 2025;8:55-64)*

Keywords

Randomized controlled trial, palatal obturator, mouth neoplasm, velopharyngeal insufficiency, speech disorder, deglutition disorder, maxillofacial prosthesis, prosthodontics.

AUDIOABSTRACTACT

INTRODUCTION

In 2023, the estimated incidences of “lips-oral cavity-pharynx” cancers in France were 30.3 cases among men and 11.9 cases among women per 100,000 person-years.[1] Of these tumors, less than 15% involve the soft palate.[2,3] Malignant tumors of the soft palate are predominantly squamous cell carcinomas, which are treated with chemoradiotherapy, radiotherapy, and/or surgery.[4,5] These oral oncologic treatments - notably surgical tumor removal, radiation necrosis, and fibrosis - may result in soft palate defects. The consequence is a continuous escape of airflow, called velopharyngeal insufficiency, that affects speech (hypernasality and unintelligibility) and swallowing (dysphagia).[6-8] Thus, the psychological and social impact of these functional consequences impairs the patients’ quality of life.

The traditional treatment of soft palate defects consists of a surgical reconstruction with flap placement, and/or a prosthetic rehabilitation with obturators, associated with speech therapy.[9] A successful surgery offers the possibility of a definitive reconstruction, using either local, regional, or free flaps.[10,11] However, the patient eligibility depends on risks associated with age, systemic disease, radiotherapy, and lack of adequate recipient vessels. Moreover, the hospital stay is long and may be associated with possible donor-site morbidity. The alternative was designed in the 19th century, before advances in surgery, is the pharyngeal obturator: a palatal plate or a removable dental prosthesis, with a posterior rigid extension that separates the oropharynx from the nasopharynx. This obturator prosthesis allows

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visual surveillance of cancer recurrence and can efficiently restore the pharyngeal closure when retention and stability are adequate.[7] The major limitation of this device is its reliance on the residual velopharyngeal muscles for permitting air passage modulation.[8] When the musculature is not mobile, the air will be either free or blocked, but in both cases the obturator will not restore phonation or swallowing function. The quality of life of the patient is further impaired by the associated psychological and social repercussions. An optimal restoration of chewing and swallowing in such patients remains of significant concern.[12]

In 2018, an obturator prosthesis incorporating a dental dam was used in one patient with a total soft palate resection, and it successfully restored artificially the sealing of the oropharynx during swallowing, and in controlling nasal airflow during speech.[13] The extension supported the artificial membrane, which mimicked the soft palate, in contact with oropharyngeal walls. As this membrane obturator seemed promising, a clinical pilot study was initiated. We hypothesized that this membrane obturator would more effectively restore speech and swallowing functions than the traditional rigid obturator, and would improve the quality of life of patients. The objective of this random crossover clinical study was to compare improvements in speech, swallowing, and quality of life improvement in patients with acquired soft palate defects wearing either the membrane obturator or the conventional rigid obturator.

MATERIALS AND METHODS

The VELOMEMBRANE (protocol CHUBX 2018/34) was approved by the National Agency for Drug Safety (ANSM) and by the French Ethics Committee for Person Protection (CPP; 2018-A02658-47) in 2019 and registered on ClinicalTrials.gov (NCT 04009811). The comprehensive protocol was previously published,[14] in accordance with the Standard Protocol Items of the Recommendations for Interventional Trials (SPIRIT). The present report follows the Consolidated Standards of Reporting Trials (CONSORT).

Briefly, the VELOMEMBRANE trial was a superiority, open-labeled, two-way, random, crossover clinical trial comparing the membrane obturator to the rigid obturator in adult patients with acquired soft palate loss. The patients wore both prostheses for 1-month periods in a random order. The trial was meticulously planned to take place in the Dental Departments of two renowned teaching hospitals: the Prosthodontics and Periodontics Department at Saint André Hospital in Bordeaux, France, and the Prosthodontics Department at Rangueil Hospital in Toulouse, France.

The main inclusion criteria were patients aged over 18 years, with acquired loss of velar or palato-velar substance, indicated for rigid obturator prosthesis rehabilitation, and eligible for dental rehabilitation with removable prosthesis. The specific exclusion criteria were allergy to acrylic resin and concomitant treatment with radiotherapy or chemotherapy.

The control intervention consisted in taking alginate impressions of the dental arches, and fabricating a palatal plate (or a removable denture if needed) with a posterior metal wire embedded in the resin to support the future oropharyngeal impression. The wire was shaped to stand 3-5 mm from the contracted tissue. The oropharyngeal impression was made using thermoplastic material (impression compound, Kerr) followed by impression paste (SS White). The patient was asked to pronounce “A” while tilting the head forward and swaying circularly from right to left, and finally to swallow a sip of water. Then the lab technician would replace the impression material with acrylic resin to obtain a rigid obturator. The plaster model was duplicated with silicone material. For the experimental membrane obturator, a small resin extension was positioned in the middle of the soft palate defect, aligned with the soft palate plane. Pins and grooves were added to ensure membrane retention and deployment. The membrane was placed using a thick dental dam (Dental Hygienic Corporation), cut to ensure a 10 mm overlap with the pharyngeal walls, effectively restoring an artificial soft palate shape.

Each prosthesis was worn for one month (including the occlusal adjustment period). Randomization of the prosthesis order was provided by the Bordeaux University Hospital Clinical Trial Unit using SAS ver. 9.2 software (SAS Institute Inc.). Participants had no financial compensation but were given both obturators at the end of the study.

The outcomes were evaluated with validated questionnaires, administered at baseline and 1 month after delivery of each prosthesis. The primary outcome was speech disability based on the overall score of the Voice Handicap Index (VHI, 30 items, maximum score 120),[15,16] exploring functional, emotional, and physical domains. The secondary outcomes were swallowing disability using the Deglutition Handicap Index (DHI, 30 items, maximum score 100) and quality of life using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (plus the QLQ-H & N35 module, maximum score 100 for both).[17-19] The Obturator Functioning scale (OFS, 15 items, scale of 5 for each question),[20] despite not being validated in French, was also submitted with the other questionnaires.

A sample size of 14 patients was planned for statistical analyses, based on the assumption of a 15 points between the rigid and membrane obturator in VHI score, a power of 90% and a significance level

of 5%. However, the trial opened shortly before the main peak of Covid in the Rangueil Hospital of Toulouse (March 2020), it was supposed to include 10 patients out of 14, but had to close during the entire study because of open space organization, followed by restoration work. The Prosthodontics and Periodontics Department at Saint André Hospital in Bordeaux was able to include the expected four participants, but the small size of the cohort did not allow to make any statistical comparisons. Therefore, only descriptive analyses were performed. VHI and DHI scores were the sum of the codes of each item; 5-point Likert scale being coded from 0 (never) to 4 (always). If two or less data for a score were missing, they were replaced by the code "2". If there were more than two missing data on a score, the score was not calculated. OFS score was the sum of the codes of each item, 5-point Likert scale being coded from 1 (absolutely no problems) to 5 (very severe problems with the obturator). EORTC QLQ-C30 and EORTC QLQ-HN35 scores were calculated according to the EORTC QLQ-C30 Scoring Manual.[21] If there was a missing data for a score, it was not calculated.

RESULTS

Because of the Covid-19 pandemic, only 4 out of 14 patients could be included. The four included participants were all women (mean 64 ±5.2 years; min=58, max=70) (Fig.1). All filled out the questionnaires (Figs. 2-4). The mean weight was 57.9 ±3.2 Kg (min=54; max=61) for a mean height of 165 ±3.4 cm (min=163; max=170). The diagnosed carcinomas had been adenoid cystic carcinoma of the soft palate, oncocytic carcinoma of the parapharynx, epidermoid carcinoma of the oropharynx, and epidermoid carcinoma of the right tonsil (Table 1). Surgically, only one patient had a maxillectomy (1.1 a.1 in Brown's classification) associated with the soft palate defect, and 2 of them had also been treated with pharyngoplasty. Three participants had undergone radiotherapy treatment years ago (≥35 GY; between 2013 and 2015). Of these, two women had been irradiated with intensity-modulated radiation therapy (IMRT), and 1 with classical external beam radiation therapy (associated with chemotherapy). Two exhibited low levels of saliva, one was still smoking 10 cigarettes per day and one used e-cigarettes.

Three participants still had a tonic remaining soft palate (Table 2). Two soft palates were asymmetrical, two were associated with mobile oropharyngeal walls, and none exhibited perforations. Two participants were fully dentate, while both others were partially edentulous at the maxilla and mandible. None of these two partially edentulous participants wore any mandibular removable partial denture at the time of the study, and only one participant had worn in the past an obturator prosthesis. Prosthetic retention could be achieved with dental clasps for all participants.

The randomization process allocated as first prosthesis two membrane obturators and two classical obturators. Neither adverse event, modification in medical treatments nor dental problems were reported during the study. No difficulties in inserting the prostheses were reported. Retention, stability and support were achieved on the delivery day. One oropharynx sealing could only be partially achieved during the month wearing a membrane obturator. Three participants reported wearing the classical obturator all day long, and one sometimes at work. Two participants wore the membrane obturator all day long, but one of them removed it for meals and after having a cold. The third one reported wearing the prosthesis 30 min a day, while the last one stopped after her injuries (described above).

Patient 1, with complete soft palate loss but mobile pharyngeal walls (Fig. 1A), showed that both obturators decreased the VHI by more than 40% and the DHI by 56% (Table 3, Figs. 2 and 3). There was almost no difference between the obturators in VHI (7%) or DHI (4%). QLQ and OFS questionnaires indicated that the voice sounded different with the membrane obturator, accompanied by difficulties in public speaking and in being understood by others. Additional complaints included oral dryness and difficulties in chewing food. The rigid obturator caused brief discomfort when inserting and removing the device.

Patient 2, with one-third of the soft palate remaining and mobile pharyngeal walls (Fig. 1B), showed that both obturators decreased the VHI by more than 25% and the DHI by around 35% (Table 3, Figs. 2 and 3). The difference between obturators was minimal for VHI (4%) but more marked for DHI (17%). QLQ and OFS questionnaires indicated persistent handicap, but at a lower level with the rigid obturator. This patient reported pain after wearing the membrane obturator. Wounds were observed on the anterolateral soft palate wall (due to friction with the extension) and at the lip commissure (caused by a clasp during removal).

Patient 3 had a central soft palate defect and mobile oropharyngeal walls, but the lateral soft palate was stitched to the tongue (Fig. 1C). With the classical obturator, the VHI decreased by 73% and the DHI by 47% (Table 3, Figs. 2 and 3). With the membrane obturator, the VHI decreased by 37% and the DHI by 18%. The membrane obturator could not adequately seal the space behind the stitched lateral walls, leaving

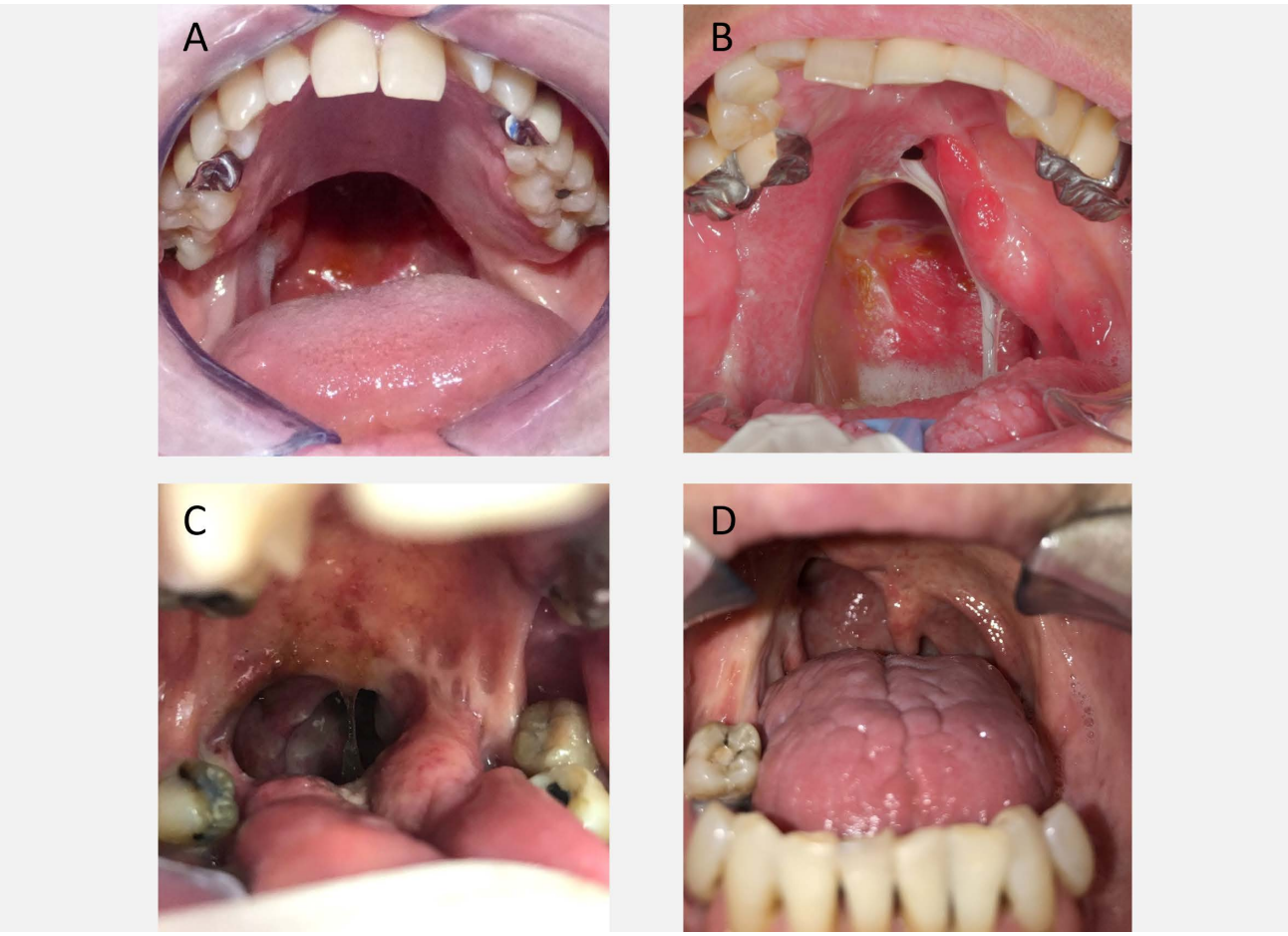

Fig 1. Intraoral photographs of soft palate defects. A) Patient 1, B) Patient 2, C) Patient 3, D) Patient 4.

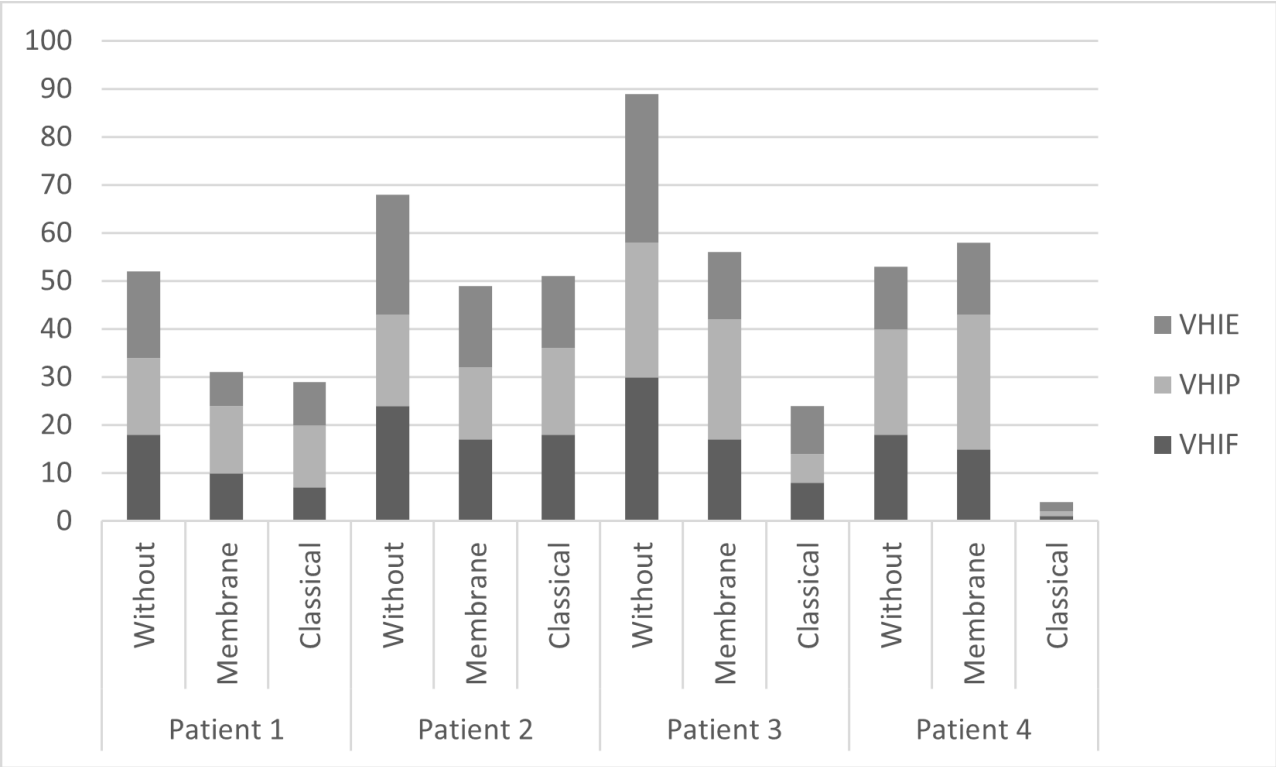

Fig 2. Voice Handicap Index and its functional (VHIF), emotional (VHIE) and physical (VIHP) domains, without obturator, with membrane obturator and with classical rigid obturator, by patient.

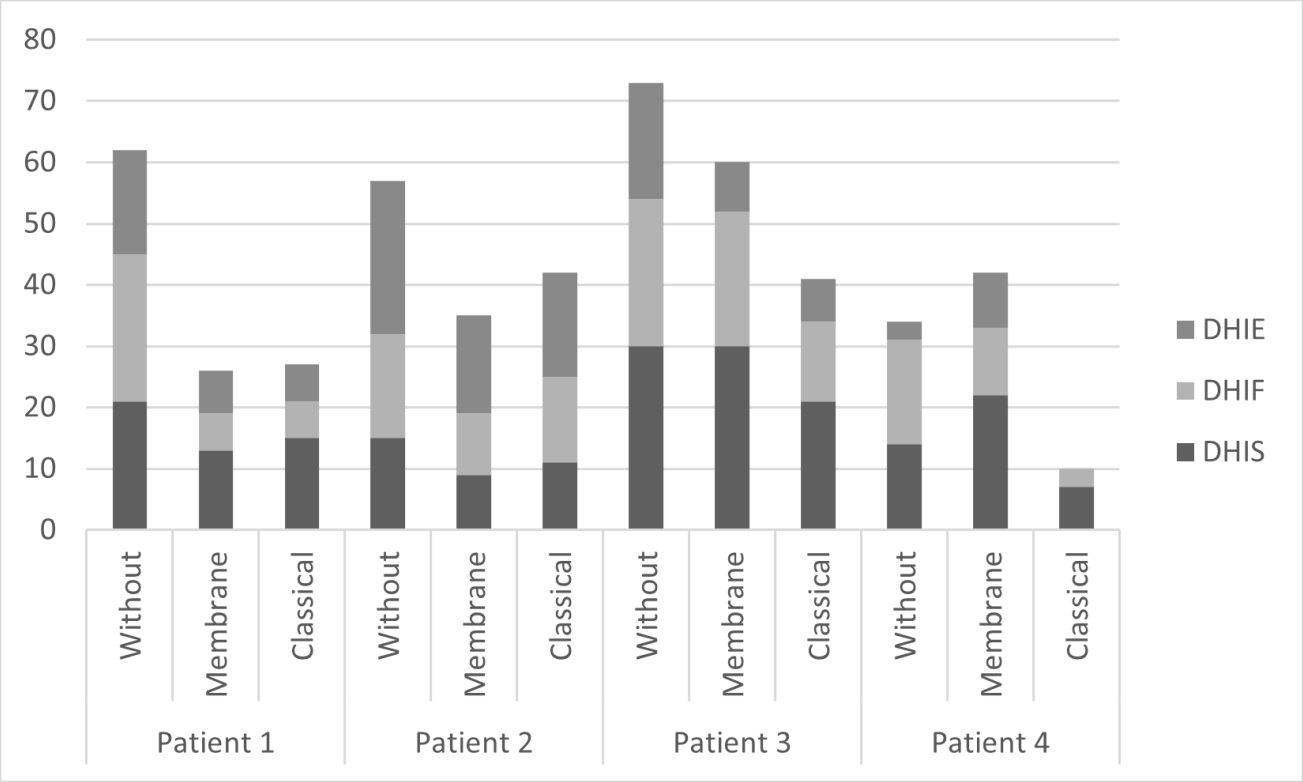

Fig 3. Deglution Handicap Index and its functional (DHIF), emotional (DHIE) and somatic (DIHS) domains, without obturator, with membrane obturator and with classical rigid obturator, by patient.

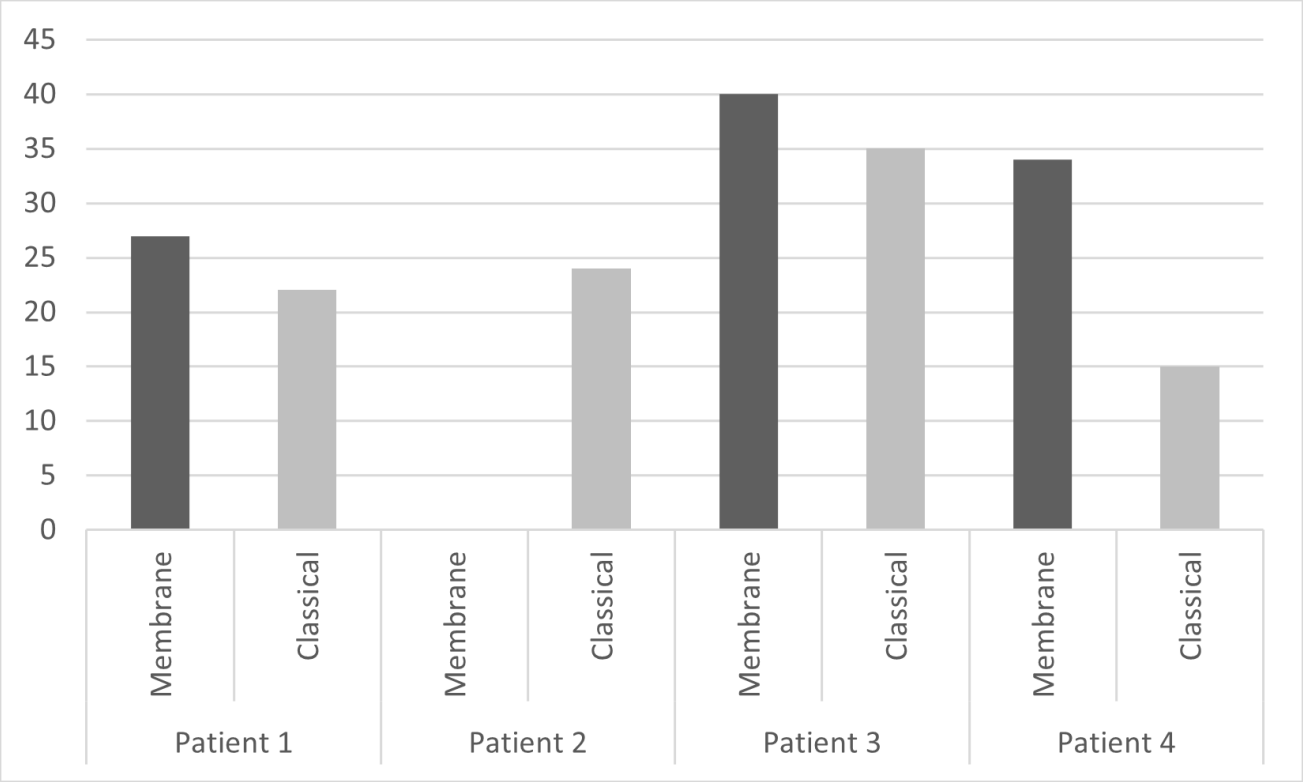

Fig 4. Obturator Functioning Scale, with membrane obturator or classical rigid obturator, by patient.

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Table 1. Medical history of participants.

Patient	Cancer	Maxillectomy	Pharyngoplasty	Osteonecrosis	Radiation therapy (≥35GY)	Chemotherapy	Current smoking habit
1	Adenoid cystic carcinoma of the soft palate	No	No	No	Yes in 2013 IMRT*	No	No
2	Oncocytic carcinoma of the parapharynx	Yes	Yes	No	No	No	No
3	Epidermoid carcinoma of the oropharynx	No	No	No	Yes in 2015 classical external beam radiation	Yes in 2015	e-cigarette 30 uses/day
4	Epidermoid carcinoma of the tonsil	No	Yes	Yes	Yes in 2015 IMRT*	No	Standard cigarettes 10/day

*Intensity-Modulated Radiation Therapy.

Table 2. Oral status of participants.

Patient	Oral opening	Soft palate loss	Remaining soft palate	Scarring flanges	Mobile oropharyngeal walls (lat/post)	Disunity post-surgery	Quantity of saliva	Consistancy of saliva	Maxillary missing teeth	Mandibular missing teeth	Mandibular removable partial denture	Previous obturator prosthesis
1	37	Total	No	No	Yes	No	Poor	Clear	No	No	No	No
2	50	Central	Tonic	Yes	Yes	Yes	Normal	Clear	No	No	No	No
3	35	Central	Tonic	Yes	No	No	Poor	Bullous	Partial class 6*	Partial class 6*	Yes but never worn	No
4	27	Right side	Tonic	Yes	Yes	Yes	Normal	Bullous	Partial class 1*	Partial class 2.1*	No	Yes

Table 3. Voice Handicap Index (VHI), Deglution Handicap Index (DHI), Obturator Functioning Scale (OFS), without obturator, with membrane obturator and with classical rigid obturator, by patient.

	Patient	Without obturator	Classic obturator	Membrane obturator	Difference Membrane/Classic
VHI	1	52	29	31	2
	2	68	51	49	-2
	3	89	24*	56	32
	4	53*	4	58	54
DHI	1	62	27	26	-1
	2	57	42	35**	-7
	3	73	41*	60	19
	4	34*	10	42*	32
OFS	1		22	27	5
	2		24	NC	NC
	3		35	40	5
	4		15	34	19

NC : Not calculated because of more than two missing data.
* One missing data.
** Two missing data.

a passage for air leakage. Major complaints were nasal speech and difficulties in public speaking with the membrane obturator. The absence of mucosal resiliency, due to the lateral soft palate being stitched to the tongue, further compromised function. Such patients typically have a nasal tone, impaired speech, and severe reflux due to a narrow swallowing passage. Even with an obturator, discomfort persists.

Patient 4, with half of the soft palate missing but mobile walls (Fig. 1D), experienced near-complete functional restoration with the classical obturator: the VHI decreased by 92% and the DHI by 69% (Table 3, Figs. 2 and 3). In contrast, the membrane obturator worsened the handicap, with a 9% increase in VHI and a 24% increase in DHI. Again, the limitation of the membrane obturator was its inability to seal the space behind the lateral walls of the soft palate.

Overall, VHI and DHI scores were markedly improved with both obturators, except in Patient 4 where the membrane obturator slightly worsened outcomes. Patients 3 and 4 achieved substantially better results with the classical obturator, whereas Patients 1 and 2 showed slight improvements with the membrane obturator. Patients reported higher OFS scores with the membrane obturator than with the classical obturator, indicating greater functional difficulties. The EORTC QLQ-C30 and QLQ-H&N35 questionnaires did not provide additional insights into health-related quality of life but are presented in the Appendix (Appendix 1).

DISCUSSION

The study could not be completed due to Covid-19 pandemic. Our hypothesis was rejected, as in the four participants, the new membrane obturator did not improve speech more than the standard obturator. The membrane obturator exhibited a similar efficacy in restoring speech and swallowing in cases with complete resection of the soft palate. In these cases, a controlled nasal air flow during speech and a pharyngeal obturation during deglutition were obtained with the dental dam in continuity with the hard palate. When the soft palate defect was partial with a mobile residual wall, the membrane obturator was less effective than the traditional obturator.

In the literature, the classical obturator was reported to function better, as indicated by higher total scores on the OFS when resection of the soft palate was limited to one third or less and resection of the hard palate to one fourth or less.20 Conversely, a non-functional partially resected soft palate may be challenging or impossible to rehabilitate with a prosthesis, potentially resulting in velopharyngeal incompetence characterized by hypernasality and nasal regurgitation of food and liquids.[22] In this study, the membrane obturator was more effective when the whole palate was missing, as the membrane had access to the full oropharyngeal area. These results are in accordance with the first case reports about the membrane obturator, as both patients had a total loss of soft palate and benefited of an improvement of the oral functions.[13,23] When the soft palate defect

was partial, the membrane obturator was less effective or worsened the handicaps, because of the difficulty of obtaining a sealing behind the residual wall.

In the literature, it has been shown that responses on the OFS related to speech understandability and difficulty pronouncing words were significantly influenced by a history of radiation therapy.[20,24] Individuals who had undergone radiation therapy were more likely to report that their speech was harder to understand and more difficult to produce.[24] However, saliva levels could not be identified as a limitation factor from the current study. Indeed, Patient 1 and 2 assessed positively the membrane obturator, but had respectively low and normal saliva levels, while Patient 3 and 4 had difficulties with this obturator, but also had respectively normal and low saliva levels. An explanation is the limited cohort and the moderate hyposalivation in the participants.

Regarding the speech perception, it has been shown that women reported more significant changes in their voice compared with men.[24] Additionally, individuals who had resections involving the soft palate were more likely to experience voice changes than those whose resections were confined to the hard palate.[20,22,24] Finally, individuals whose prostheses were retained using a removable partial denture were more likely to report that their voice had remained unchanged since surgery, compared with those with retention through a complete upper denture or an implant-supported prosthesis.[24] For these reasons, the low speech satisfaction in the current study was predictable. These parameters were also shown to affect eating perception.[24]

Several limitations appeared about the membrane obturator. First, the design of the membrane depended heavily on the defect shape, and did not allow to draw clear design recommendations. A specific design of the membrane obturator could probably have solved the geometry issues raised in Patient 3 and 4, but was not conceived at the time of the study. Second, once the rigid resin extension was placed on the plate, modifications could only be minors as removing retention groove or pin would lead to the necessity for e-designing the membranes. This issue was highlighted in Patient 2, who suffered from friction wounds, with limited possibilities of improvement in the study timeline. Third, the dams lost their elasticity after a week in the mouth, being less effective/comfortable, and needed to be replaced. The practitioners had to prepare some personalized dams and to teach the patient how to replace them. The study showed however that the all participants were able to replace the dams by themselves. But on the long run, some issues will remain, as the patient would have had to be independent, buying dental dams (without expecting healthcare reimbursement) and shaping the dams for replacement.

The major limitation of this study was the poor recruitment due to the Covid-19 pandemic. The small cohort prevented meaningful statistical analysis and comparison with other studies reporting item-specific percentages. Analysis of the QLQ-C30 and QLQ-HN35 quality of life questionnaires was not provided in detail for the sake of conciseness, but previous research has shown correlations between these measures and OFS scores.[22]

Additional clinical limitations arose during the study design but were maintained to facilitate the rapid inclusion of eligible patients. First, evaluating the efficacy of an obturator with a provisional prosthesis may be problematic, as obturator prostheses require optimal stability to be effective. Indeed, the pharyngeal extension amplifies prosthetic movements at the oral level. A comprehensive treatment including fixed and removable prosthodontics would have exceeded the inclusion period. Second, no relining step was performed to minimize follow-up visits prior to questionnaire assessment, although relining is often required to optimize airflow control in definitive obturators. Third, speech therapy was not scheduled after prosthetic fitting, despite being recommended, because the short interval between prosthesis delivery (one month for each device) and therapy outcomes would have interfered with the patients' adaptation process.

CONCLUSION

The membrane obturator appears to be a promising alternative for patients with a fully resected soft palate who are not satisfactorily treated with a rigid obturator. The further development of this membrane obturator will rely on advances in biomaterials, such as elastomer 3D printing. As study inclusion was impacted by the Covid-19 pandemic, a larger clinical trial is still needed to establish clear clinical protocols and refine indications.

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Appendix 1. EORTC QLQ-C30 and EORTC QLQ-HN35 scores by patient, according to obturator.

	Patient 1			Patient 2			Patient 3			Patient 4		
EORTC QLQ-C30	**Without**	**Classical**	**Membrane**	**Without**	**Classical**	**Membrane**	**Without**	**Classical**	**Membrane**	**Without**	**Classical**	**Membrane**
Global Health status	50	NC	83	67	33	NC	83	NC	NC	NC	100	33
Physical functioning	93	93	93	100	93	93		87		93	100	100
Role functioning	33	100	67	83	83	100	100	83	50	100	100	100
Emotional functioning	50	92	92	83	67	75	50	75	58	83	100	67
Cognitive functioning	83	100	100	83	83	83	100	83	100	83	100	100
Social functioning	33	100	100	100	83	83	100	100	83	100	100	100
Fatigue	22	0	0	33	33	33	33	33	44	22	0	22
Nausea and vomiting	33	17	0	0	0	0	0	0	0	0	0	33
Pain	33	17	0	17	17	0	17	17	33	0	0	0
Dyspnea	67	0	0	0	33	33	0	0	0	0	0	0
Insomnia	33	0	33	0	0	0	100	33	67	0	0	33
Appetite loss	33	0	0	0	33	0	0	33	33	0	0	0
Constipation	0	0	0	0	0	0	100	100	100	0	0	0
Diarrhoea	0	0	0	0	0	0	0	0	0	0	0	0
Financial difficulties	0	0	0	33	33	33	0	0	0	33	33	0
EORTC QLQ-HN35	**Without**	**Classical**	**Membrane**	**Without**	**Classical**	**Membrane**	**Without**	**Classical**	**Membrane**	**Without**	**Classical**	**Membrane**
Pain	33	0	25	33	17	17	33	0	8	33	0	33
Swallowing	58	33	25	25	8	25	33	8	42	17	17	42
Senses problems	50	50	17	0	0	17	0	17	0	0	0	0
Speech problems	78	22	0	22	22	33	67	22	56	33	0	22
Trouble with social eating	58	0	8	42	17	42	42	8	25	0	0	8
Trouble with social contact	20	0	0	53	33	47	7	0	7	0	0	0
Less sexuality	33	0	0	33	50	33	0	0	0	0	0	0
Teeth	0	0	0	0	33	0	0	0	33	67	33	0
Opening mouth	67	0	33	0	0	0	0	33	67	67	33	33
Dry mouth	100	100	100	33	0	33	100	33	67	33	0	33
Sticky saliva	33	33	67	33	33	33	67	33	100	33	33	0
Coughing	67	67	67	33	33	33	33	0	33	33	0	0
Felt ill	33	0	0	0	0	0	0	0	0	0	0	0
Pain killers	100	0	100	0	0	0	100	0	100	100	100	100
Nutritional supplements	100	0	0	0	0	100	0	0	NC	0	0	0
Feeding tube	100	0	0	0	0	0	100	100	100	0	0	0
Weight loss	100	0	0	0	0	0	0	0	100	0	0	0
Weight gain	0	100	0	100	100	100	0	0	0	0	0	0

NC: not calculated because of missing data.